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Sätric™ Tablets (metronidazole USP) 250 mg

INDICATIONS AND USAGE: *Symptomatic Trichomoniasis:* Sätric is indicated for the treatment of symptomatic trichomoniasis in females and males when the presence of trichomoniasis has been confirmed by appropriate laboratory procedure (wet mount smears and/or cultures).

Asymptomatic Trichomoniasis: Sätric is indicated in the treatment of asymptomatic females when the organism is associated with endocervicitis, cervicitis, or cervical erosion. Since there is evidence that presence of the trichomonad can interfere with accurate assessment of abnormal cytological smears, additional smears should be performed after eradication of the parasite.

Treatment of Asymptomatic Consorts: *T. vaginalis* infection is a venereal disease. Therefore, asymptomatic sexual partners of treated patients should be treated simultaneously if the organism has been found to be present in order to prevent reinfection of the partner. The decision as to whether to treat an asymptomatic male partner with a negative culture or one in whom no culture has been attempted is an individual one. In making this decision, it should be noted that there is evidence that women may become reinfected if the consort is not treated. Also, since there can be considerable difficulty in isolating the organism from the asymptomatic male carrier, negative smears and cultures cannot be relied upon in this regard. In any event, the consort should be treated with Sätric in cases of reinfection.

Amebiasis: Sätric is indicated in the treatment of acute intestinal amebiasis (amebic dysentery) and amebic liver abscess.

CONTRAINdications: Sätric is contraindicated in patients with active organic disease of the central nervous system. (See *Adverse Reactions*.)

Sätric is contraindicated during the first trimester of pregnancy. (See *Warnings*.)

Sätric is also contraindicated in patients with a prior history of hypersensitivity to metronidazole.

WARNINGS: *Convulsive Seizures and Peripheral Neuropathy:* Convulsive seizures and peripheral neuropathy, the latter characterized mainly by numbness or paresthesia of an extremity, have been reported in patients treated with metronidazole. The appearance of abnormal neurological signs demands the prompt discontinuation of Sätric therapy. Sätric should be administered with caution to patients with central nervous system diseases.

Tumorigenicity Studies in Rodents: Metronidazole has shown evidence of tumorigenic activity in a number of studies involving chronic, oral administration in mice and rats.

Most prominent among the effects in the mouse was the promotion of pulmonary tumorigenesis. This has been observed in all five reported studies of that species, including one study in which the animals were dosed on an intermittent schedule (four rats/rat during the first week only). The published results of one of the mouse studies indicate an increase in the incidence of malignant lymphomas as well as pulmonary neoplasms associated with lifetime feeding of the drug. All these effects are statistically significant.

Two long-term toxicity studies in the rat have been completed. There was a statistically significant increase in the incidence of various neoplasms, particularly mammary tumors, among female rats administered metronidazole over that noted in the concurrent female control groups. Two lifetime tumorigenicity studies in hamsters have been performed and reported to be negative.

PRECAUTIONS: General: Patients with severe hepatic disease metabolize metronidazole slowly, with resultant accumulation of metronidazole and its metabolites in the plasma. Accordingly, for such patients, doses below those usually recommended should be administered cautiously.

Known or previously unrecognized candidiasis may present more prominent symptoms during therapy with Sätric and requires treatment with a candidicidal agent.

Laboratory Tests: Sätric (metronidazole) is a nitroimidazole and should be used with care in patients with evidence of, or history of blood dyscrasias. A mild leukopenia has been observed during its administration; however, no persistent hematologic abnormalities attributable to metronidazole have been observed in clinical studies. Total and differential leukocyte counts are recommended before and after therapy for trichomoniasis and amebiasis, especially if a second course of therapy is necessary.

Drug Interactions: Metronidazole has been reported to potentiate the anticoagulant effect of coumarin and warfarin resulting in a prolongation of prothrombin time. This possible drug interaction should be considered when Sätric is prescribed for patients on this type of anticoagulant therapy.

Alcoholic beverages should not be consumed during Sätric therapy because abdominal cramps, nausea, vomiting, headache, and flushing may occur.

Drug/Laboratory Test Interactions: Metronidazole may interfere with certain chemical analyses for serum glutamic dehydrogenase, transaminase, and in decreased values. Values of zero may be observed.

Contraindications: (See *Contraindications*.)

Pregnancy: Teratogenic Effects:—Pregnancy Category B. Metronidazole crosses the placental barrier and enters the fetal circulation rapidly. Reproduction studies have been performed in rabbits and rats at doses up to five times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to metronidazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, and because metronidazole is a carcinogen in rodents, this drug should be used during pregnancy only if clearly needed. (See *Contraindications*.)

Use of Sätric for trichomoniasis in the second and third trimesters should be restricted to those in whom local palliative treatment has been inadequate to control symptoms.

Nursing Mothers: Because of the potential for tumorigenicity shown for metronidazole in mouse and rat studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Metronidazole is secreted in breast milk in concentrations similar to those found in plasma.

Pediatric Use: Safety and effectiveness in children have not been established, except for the treatment of amebiasis.

ADVERSE REACTIONS: By far the most common adverse reactions have been referable to the gastrointestinal tract, particularly nausea, sometimes accompanied by headache, anorexia and occasionally vomiting, diarrhea, epigastric distress and abdominal cramping; constipation has also been reported. A metallic, sharp, unpleasant taste is not unusual. Furry tongue, glossitis and stomatitis have occurred; these may be associated with a sudden overgrowth of *Candida* which may occur during effective therapy. Proliferation of *Candida* also may occur in the vagina.

A moderate leukopenia may be observed occasionally. If this occurs, the total leukocyte count may be expected to return to normal after the course of medication is completed.

If patients receiving Sätric (metronidazole) drink alcoholic beverages, they may experience abdominal distress, nausea, vomiting, flushing, or headache. A modification of the taste of alcoholic beverages has also been reported.

Dizziness, tinnitus, vertigo, ataxia, convulsive seizures, and peripheral neuropathy have been reported. Numbers or paroxysms of an extreme and disabling joint pain sometimes resembling "serum sickness" have been experienced, as have confusion, irritability, depression, weakness, insomnia, and a mild erythematous eruption.

Urticaria, flushing, nasal congestion, dryness of the mouth (or vagina or vulva), pruritis, dysuria, cystitis, and a sense of pelvic pressure have been reported. Very rarely dyspareunia, fever, polyuria, incontinence, decrease of libido, pruritis, and pyuria have occurred in patients receiving the drug.

Instances of darkened urine have been reported and this manifestation has been the subject of a special investigation. Although the pigment which is probably responsible for this phenomenon has not been positively identified, it is almost certainly a metabolite of metronidazole. It seems certain that it is of no clinical significance and may be encountered only when Sätric (metronidazole) is administered in higher-than-recommended doses.

Flattening of the T-wave may be seen in electrocardiographic tracings.

DOSAGE AND ADMINISTRATION: *Trichomoniasis: In The Female:* The recommended dosage is one 250 mg tablet orally 3 times daily for 7 days.

CAUTION: Federal law prohibits dispensing without prescription.

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